UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
WILLIAM PRICE, an individual, Plaintiff, vs. AUXILIUM PHARMACEUTICALS, INC., CPEX PHARMACEUTICALS, INC., and DPT LABORATORIES, LTD., Defendants.	COMPLAINT AND JURY DEMAND Civil Action No.: 1:14-cv-10192

Plaintiff WILLIAM PRICE ("Plaintiff") alleges as follows:

1. Plaintiff is a citizen of the State of North Carolina.

2. Defendants' conduct in designing, licensing, manufacturing, distributing, selling, and marketing the prescription drug Testim® has caused Plaintiff to suffer physical injuries and damages including (without limitations) a stroke, and related sequelae, pain and suffering, bodily impairment, mental anguish and diminished enjoyment of life, as well as economic loss and other special damages.

Defendants

3. Defendant AUXILIUM PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business at 640 Lee Road, Chesterbrook, Pennsylvania 19087. At all relevant times, Defendant AUXILIUM PHARMACEUTICALS, INC. was engaged in the research, development, sales and marketing of pharmaceutical products including Testim® (testosterone gel) ("Testim"), and was and is the holder of the exclusive right to make and sell Testim.

4. Defendant CPEX PHARMACEUTICALS, INC. is a Delaware corporation with its principal place of business at 1105 North Market Street, Suite 1300, Wilmington, Delaware. Defendant CPEX PHARMACEUTICALS, INC. was engaged in the research, development, sales and marketing of pharmaceutical products including Testim. On information and belief, at all relevant times, Defendant CPEX PHARMACEUTICALS, INC. provided and provides Defendant AUXILIUM PHARMACEUTICALS, INC. with the exclusive license to make and sell Testim.

5. Defendant DPT LABORATORIES, LTD. is a Texas corporation with its principal place of business at 318 McCullough, San Antonio, TX 78215. On information and belief, at all relevant times, Defendant DPT LABORATORIES, LTD. manufactured and manufactures Testim for Defendant AUXILIUM PHARMACEUTICALS, INC. for sale in the United States of America.

6. On information and belief, at all relevant times, Defendants AUXILIUM PHARMACEUTICALS, INC., CPEX PHARMACEUTICALS, INC., and DPT LABORATORIES, LTD. ("Defendants") were and are authorized to do business in the State of Illinois and were and are engaged in substantial commerce and business activity in the State of Illinois. At all relevant times, Defendants were involved in the sale and marketing of pharmaceutical products including Testim in the State of Illinois.

7. At all relevant times, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of the other Defendant herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other Defendant, knowing that its conduct constituted a breach of duty owed to Plaintiff.

8. At all times herein alleged, the officers and directors of Defendants participated in, authorized and directed the production and promotion of Testim when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of

Testim and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff.

JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000.00 exclusive of interest and costs.

10. Defendants have transacted and conducted business within the State of Illinois, have derived substantial revenue from goods and products used in the State of Illinois, have derived substantial revenue from interstate commerce, and expected, or should have expected, their acts to have consequences within the State of Illinois. This Court has personal jurisdiction over these defendants.

11. Direct filing in this judicial district in MDL 2545 for all pre-trial purposes is proper pursuant to the Honorable Mathew F. Kennelly's October 24, 2014 Case Management Order No.12.

FACTS

Testosterone and Hypogonadism

12. Testosterone is a primary androgenic hormone responsible for normal growth, development of the male sex organs, and maintenance of secondary sex characteristics.

13. The hormone plays a role in sperm production, fat distribution, maintenance of muscle strength and mass, and sex drive.

14. Hypogonadism is a specific condition of the sex glands, which in men may involve the diminished production or nonproduction of testosterone.

15. In men, testosterone levels normally begin a gradual decline after the age of thirty.

16. However, this age-related decrease in testosterone levels is not necessarily a sign of any disease and does not rise to the level of diagnosis of hypogonadism in a majority of men.

17. Further, testosterone levels can fluctuate greatly depending on many factors, including sleep, time of day, and medication. Thus, even otherwise healthy men may exhibit low or borderline levels of testosterone depending on circumstances at the time of the test.

Low Testosterone – a Disease Made Up for Defendants' Profits

18. Defendants participated in advertising campaigns designed to convince men that they suffered from low testosterone. Defendants participated in national disease awareness media blitzes that purported to educate male consumers about the signs of low testosterone. The national marketing campaigns consisted of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential testosterone users, and online media.

19. Defendants' advertisements suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include listlessness, increased body fat, and moodiness—all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone.

20. Defendants advertise their product through a website purporting to provide useful information regarding claimed symptoms of "Low T," advising potential patients in a "Doctor Discussion Guide" how they should be discussing Low T with their physicians, and, ultimately, suggesting a purportedly safe and effective solution – Testim.

21. Defendants have also sought to convince primary care physicians that low testosterone levels are widely under-diagnosed, and that conditions associated with normal aging could be caused by low testosterone levels.

22. Defendants' marketing campaigns have been very successful, convincing millions of men that they need testosterone replacement therapy. As a result of Defendants' "disease mongering," as termed by Dr. Adriane Fugh-Berman of Georgetown University Medical Center, the number of individuals diagnosed with Low T has increased exponentially.

23. While running their campaigns for the awareness of low testosterone as a disease, Defendants promoted and promote their testosterone products as easy to use topical testosterone replacement therapies.

24. Defendants convinced millions of men to discuss testosterone replacement therapy with their doctors, and consumers and their physicians relied on Defendants' promises of safety and ease. Although prescription testosterone replacement therapy had been available for years, millions of men who had never been prescribed testosterone flocked to their doctors and pharmacies.

25. However, these men were enticed to take dangerous medication that carries no benefit because many, if not most, of these men did not suffer from any testosterone-related condition that required medical intervention.

26. A study published in the Journal of the American Medical Association ("JAMA") in August 2013 entitled "Trends in Androgen Prescribing in the United States, 2001-2011" indicated that many men who get testosterone prescriptions have no evidence of hypogonadism. For example, one third of men prescribed testosterone had a diagnosis of fatigue, and one quarter of men did not even have their testosterone levels tested before they received a testosterone prescription.

27. According to Shannon Pettypiece, *Are Testosterone Drugs the Next Viagra?,* Bloomberg Businessweek, May 10, 2012, estimates indicate that sales are expected to triple in the next few years, bringing in over $5 billion by the year 2017.

Defendants' Testim

28. At all relevant times, Testim Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Testim as a testosterone replacement therapy.

29. Testim is a gel containing testosterone. It is applied to the upper arms or shoulders. The drug enters the body through transdermal absorption.

30. The FDA approved Testim for the treatment of adult males who have low or no testosterone. After the FDA approval, Testim Defendants widely advertised and marketed Testim as safe and effective testosterone replacement therapy.

31. The increase in the number of patients misdiagnosed with hypogonadism as a result of Defendants' advertising efforts has resulted in over $233 million in annual sales of Testim. Testim is the third highest selling androgen drug in the United States.

The Dangers of Testosterone Therapy

32. Testosterone therapies, including Testim, are not safe drugs, but products which cause life-threatening problems including blood clots, strokes and heart attacks.

33. There have been a number of studies suggesting that testosterone in men increases the risk of serious side effects:

a. In 2010, a New England Journal of Medicine Study entitled "Adverse Events Associated with Testosterone Administration" was discontinued after an exceedingly high number of men in the testosterone group suffered adverse events.

b. In November of 2013, a JAMA study entitled "Association of Testosterone Therapy with Mortality, Myocardial Infarction, and Stroke in Men with Low Testosterone Levels" indicated that testosterone therapy raised the risk of death, heart attack and stroke by about 30%.

c. On January 29, 2014, a study was released in PLOS ONE entitled "Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men." This study indicated that testosterone increases the risk of heart attacks in men over sixty-five years old by 200% and in men younger than sixty-five with a previous diagnosis of heart disease by up to 300%.

34. Secondary exposure to testosterone can cause side effects in others. In 2009, the FDA issued a black box warning for testosterone prescriptions, advising patients of reported

virilization in children who were secondarily exposed to the gel. Testosterone may also cause physical changes in women exposed to the drug and cause fetal damage with pregnant women who come into secondary contact with testosterone.

Defendants Misrepresented and Failed to Warn of the Dangers of Testim

35. Defendants' marketing strategy has been to aggressively market and sell Testim by misleading potential users about the prevalence and symptoms of low testosterone. Defendants failed to protect users from serious dangers that Defendants knew, or should have known, can result from the use of the Testim.

36. Defendants successfully marketed Testim by undertaking campaigns designed to create a consumer perception that low testosterone is prevalent among U.S. men and that symptoms previously associated with other physical and mental conditions, such as aging, stress, depression, and lethargy were actually attributable to low testosterone. Defendants knew, or should have known, these assertions to be false, and had no reasonable grounds to believe them to be true.

37. Defendants' advertising programs sought to create the image and belief by consumers and their physicians that the use of Testim was a safe method of alleviating their symptoms, had few side effects and would not interfere with their daily lives, even though Defendants knew, or should have known, these assertions to be false, and had no reasonable grounds to believe them to be true.

38. Defendants purposefully downplayed, understated and outright ignored the health hazards and risks associated with using Testim. Defendants deceived potential users of Testim by overemphasizing and misrepresenting the prevalence and dangers of low testosterone, while downplaying known adverse and serious health effects of testosterone therapies, including Testim.

39. Defendants concealed materially relevant information from potential testosterone users and minimized user and prescriber concern regarding the safety of Testim.

40. In particular, in the warnings Defendants gave and give in their commercials, online and print advertisements, Defendants had failed and fail to mention significant side effects of Testim and had falsely represented and represent that Defendants have adequately tested it for all likely side effects.

41. Defendants did not provide adequate warnings to Plaintiff's doctors, Plaintiff, the healthcare community and the general public about the increased risk of serious adverse events that are described herein.

42. The product warnings for Testim in effect during the time period Plaintiff used the Testim were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert prescribing physicians, as well as Plaintiff, of the serious risks associated with these drugs.

43. As a result of Defendants' advertising and marketing, and representations about their products, men in the United States, including Plaintiff, pervasively sought out and seek out prescriptions for testosterone, including Testim.

Testim Caused Plaintiff's Injuries

44. As a direct and proximate result of Defendants' conduct, Plaintiff's physician prescribed Testim to Plaintiff, and Plaintiff used Testim.

45. In choosing to take Testim, Plaintiff and Plaintiff's physician relied on claims made by Defendants that low testosterone is a disease that requires pharmaceutical drug treatment.

46. In choosing to take Testim, Plaintiff and Plaintiff's physician relied on claims made by Defendants that testosterone had been clinically shown to safely and effectively raise testosterone levels.

47. Had Plaintiff and/or Plaintiff's physician been adequately warned of the potential life-threatening side effects of Testim, Plaintiff would not have purchased or taken these drugs.

48. As a result of using the Testim, Plaintiff was caused to suffer continuing bodily injury, including (without limitations) a stroke, and was thus caused to sustain severe and permanent personal injuries, pain, suffering, and mental anguish.

DISCOVERY RULE & FRAUDULENT CONCEALMENT

49. The nature of Plaintiff's injuries and damages, and their relationship to Testim, was not discovered, and through reasonable care and due diligence could not have been discovered, by Plaintiff, until a time less than three years before the filing of this Complaint.

50. Defendants are estopped from asserting a statute of limitations defense because all Defendants fraudulently concealed from Plaintiff the nature of Plaintiff's injury and the connection between the injury and all Defendants' tortious conduct.

STATE CAUSES OF ACTION ONLY

51. Plaintiff pursues only state-law claims. Plaintiff is not making in this case any claims that raise a federal question.

FIRST CAUSE OF ACTION
STRICT LIABILITY: FAILURE TO WARN

52. Plaintiff incorporates by reference and realleges each paragraph set forth above.

53. Testim was defective due to inadequate warnings or instruction for use, both prior to marketing and post-marketing. Defendants knew or should have known that Testim created significant risks of serious bodily harm and death to consumers. Defendants failed to adequately warn consumers and their healthcare providers of such risks.

54. Because of Defendants' failure to provide adequate warnings with their product, Plaintiff used Testim, which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce. Testim is the legal cause of Plaintiff's serious physical injuries, harm, damages and economic loss. Plaintiff will continue to suffer such harm, damages and economic loss in the future.

SECOND CAUSE OF ACTION
STRICT LIABILITY: DEFECTIVE DESIGN

55. Plaintiff incorporates by reference and realleges each paragraph set forth above.

56. Testim was in a defective condition and unreasonably dangerous due to inadequate testing, warnings and instructions for use, which created significant health risks and threat of serious bodily harm to consumers at large, including Plaintiff.

57. Defendants are strictly liable for Testim which was in a defective condition and unreasonably dangerous because of the inadequate and incomplete testing, and warnings and instructions for use to Plaintiff and Plaintiff's physicians.

58. Defendants are strictly liable for Testim which was in a defective condition and unreasonably dangerous because of its design.

59. The risk-utility of Testim as a treatment for a contrived and pharmaceutical industry-created and -driven condition known as "Low T" was such that Testim presented substantial and unreasonable risk with unproven safety or utility.

60. Consumers, including Plaintiff and Plaintiff's physicians, had the expectation that Testim, as designed, tested, and placed within the stream of interstate commerce, was safe and effective for the uses outlined by the Defendants, detailed to physicians, and advertised to the public at large by way of direct-to-consumer advertising.

61. Plaintiff used Testim, which the Defendants manufactured, designed, sold, supplied, marketed or otherwise introduced into the stream of commerce, and Testim caused serious physical injuries to Plaintiff. Defendants' defective design and testing of Testim is the legal cause of Plaintiff's serious physical injuries, harm, damages and economic loss. Plaintiff will continue to suffer such harm, damages and economic loss in the future.

THIRD CAUSE OF ACTION
NEGLIGENCE

62. Plaintiff incorporates by reference and realleges each paragraph set forth above.

63. Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, labeling, marketing, sale and/or distribution of Testim. In particular, they had a duty to assure that their product did not pose an unreasonable risk of bodily harm and adverse events.

64. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, marketing, or distribution of Testim in that they knew or should have known that Testim could cause significant bodily harm or death and was not safe for use by certain types of consumers.

65. Defendants failed to exercise ordinary care in the labeling of Testim and failed to issue to consumers and their healthcare providers adequate warnings concerning the risks of serious bodily injury or death due to the use of Testim.

66. Despite the fact that Defendants knew or should have known that Testim posed a serious risk of bodily harm to consumers, Defendants unreasonably continued to manufacture and market Testim and failed to exercise reasonable care with respect to post-sale warnings and instructions for safe use.

67. At all relevant times, it was foreseeable to Defendants that consumers like Plaintiff would suffer injury as a result of their failure to exercise ordinary care as described above.

68. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered physical injuries, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

FOURTH CAUSE OF ACTION
FRAUD

69. Plaintiff incorporates by reference and realleges each paragraph set forth above.

70. Defendants knowingly and intentionally made materially false and misleading representations to Plaintiff's healthcare providers and to the public, to the effect that Testim was safe for use and that their labeling, marketing and promotional materials fully described all known risks associated with their products.

71. Defendants' representations were in fact false. Testim is not safe for use and Defendants' labeling, marketing and promotional materials did not fully describe all known risks of these products.

72. Defendants had actual knowledge that Testim created an unreasonable risk of serious bodily injury and death to consumers, including the risk of the injury that Testim caused in Plaintiff.

73. Defendants knowingly and intentionally omitted this information from their labeling, marketing, and promotional materials and instead labeled, promoted and marketed their products as safe for use in order to increase and sustain sales.

74. When Defendants made representations that Testim was safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, Plaintiff's physicians and the public, the fact that Testim was not safe for use, and causes serious side effects, including the injuries that Testim caused in Plaintiff.

75. Defendants had a duty to fully disclose the risks associated with the use of Testim, including the risk of the injuries that Testim caused in Plaintiff. Defendants had superior knowledge of these facts that were material to the decisions of Plaintiff and Plaintiff's healthcare providers to use Testim.

76. Plaintiff and Plaintiff's healthcare providers reasonably and justifiably relied on the Defendants' representations that Testim was safe for use and that Defendants' labeling, marketing and promotional materials fully described all known risks associated with these products.

77. Plaintiff did not know, and could not have learned of the facts that the Defendants omitted and suppressed. The facts suppressed and concealed by the Defendants are material. Had Plaintiff and Plaintiff's healthcare providers known the truth concerning the risks associated with the use of Testim, Plaintiff would not have used Testim.

78. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was prescribed and used Testim, and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

79. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such, Plaintiff is entitled to exemplary damages.

FIFTH CAUSE OF ACTION
FRAUD: CONCEALMENT, SUPPRESSION OR OMISSION OF MATERIAL FACTS

80. Plaintiff incorporates by reference and realleges each paragraph set forth above.

81. Defendants omitted, suppressed, or concealed material facts concerning the dangers and risks associated with the use of Testim, including but not limited to the risks of the injuries that Testim caused in Plaintiff, and the fact that safer alternatives were available. Further, Defendants purposely downplayed and understated the serious nature of the risks associated with use of Testim in order to increase and sustain sales.

82. As a direct and proximate result of Defendants' concealment of material facts, Plaintiff was prescribed and used Testim and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

83. The foregoing acts, conduct and omissions of Defendants were vile, base, willful, malicious, wanton, oppressive and fraudulent, and were done with a conscious disregard for the health, safety and rights of Plaintiff and other users of Defendants' products, and for the primary purpose of increasing Defendants' profits. As such Plaintiff is entitled to exemplary damages.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

84. Plaintiff incorporates by reference and realleges each paragraph set forth above.

85. Defendants supplied the public and Plaintiff's healthcare providers with materially false and incomplete information with respect to the safety of Testim.

86. In supplying this false information, Defendants failed to exercise reasonable care.

87. The false information communicated by Defendants to Plaintiff and Plaintiff's healthcare providers was material, and Plaintiff and Plaintiff's healthcare providers justifiably relied in good faith on the information to Plaintiff's detriment.

88. As a direct and proximate result of Defendants' misrepresentations, Plaintiff was prescribed and used Testim and has suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

89. Plaintiff incorporates by reference and realleges each paragraph set forth above.

90. Prior to the time that Plaintiff used Testim, Defendants impliedly warranted to Plaintiff and Plaintiff's agents and physicians that Testim was of merchantable quality and safe and fit for the use for which they were intended.

91. Plaintiff was and is unskilled in the research, design and manufacture of Testim and reasonably relied entirely on the skill, judgment and implied warranty of the Defendants in using Testim.

92. Testim was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that Testim has dangerous propensities when used as intended and will cause severe injuries to users.

93. As a result of the abovementioned breach of implied warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

EIGHTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

94. Plaintiff incorporates by reference and realleges each paragraph set forth above.

95. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that

Testim is safe, effective, fit and proper for its intended use. Plaintiff purchased Testim relying on these warranties.

96. In utilizing Testim, Plaintiff relied on the skill, judgment, representations, and foregoing express warranties of Defendants. These warranties and representations were false in that Testim is unsafe and unfit for their intended uses.

97. As a result of the abovementioned breach of express warranties by Defendants, Plaintiff suffered injuries and damages as alleged herein.

NINTH CAUSE OF ACTION
VIOLATION OF CONSUMER PROTECTION LAW

98. Plaintiff incorporates by reference and realleges each paragraph set forth above.

99. This Complaint is filed and these proceedings are instituted pursuant to applicable consumer protection law including (without limitations) N.C. Gen. Stat. § 75-1 *et seq*., to obtain injunctive relief, any other relief this Court deems proper, and attorneys' fees from Defendants.

100. Defendants' acts and business practices constitute unlawful methods of competition and unfair or deceptive acts within the meaning of applicable law including but not limited to the following:

a. Representing to Plaintiff, Plaintiff's physicians and the general public that Testim was safe, fit and effective for all patients, knowing that said representations were false;

b. Concealing from Plaintiff, Plaintiff's physicians and the general public that Testim had a serious propensity to cause injuries to users;

c. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Testim was safe, and had fewer side effects and adverse reactions than other options for treating symptoms of low testosterone, even though the Defendants knew these to be false, and/or had no reasonable grounds to believe them to be true;

d. Purposely downplaying and understating the health hazards and risks associated with Testim.

101. Defendants' acts and business practices constitute unlawful methods of competition and unfair or deceptive acts within the meaning of applicable law. Plaintiff demands that Defendants immediately cease the illegal conduct alleged herein.

102. The illegal conduct alleged herein is continuing and there is no indication that Defendants will refrain from such activity in the future.

103. Plaintiff is entitled to injunctive relief, attorneys' fees and any other relief this Court deems proper.

PRAYER

WHEREFORE, Plaintiff prays for relief as follows:

1. For an injunction prohibiting Defendants from engaging in conduct which violates the applicable consumer protection laws.

2. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;

3. Past and future medical expenses, income, and other economic damages in an amount to be determined at trial of this action;

4. Punitive damages in an amount to be determined at trial of this action;

5. Pre- and post-judgment interest;

6. Attorneys' fees, expenses, and costs; and

7. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all issues.

DATED: December 19, 2014

Respectfully Submitted,

/s/ David Markevitch
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